

09/643458

Table 2. Antiserum Reactivity to Immunized Peptides from Pig, Rat, and Rabbit Immunized with rAd5

Animal I.D.	Timepoint	Peptide:	Biosensor results in Response units (RU)						
			HVR1	HVR2	HVR3	HVR4	HVR5	HVR6	HVR7
Pig									
Ozle (6 months post)	Pre post		³ [456]	⁴ [208] [141]	³ [576]	³ [212]	³ [143]	⁴ [205]	
RAT									
Normal rat serum (NRS)	NRS		47	44 76 25 105	46 [35]	60.5 24	38 [87]	34 [216]	
Pooled rat serum from six rats (12 month post)	post		[456]						
RABBIT									
Normal rabbit serum (NRBS)	NRBS		9	7.5 ND 46 115	6.8 [204]	5.5 47	ND 92	ND [838]	
Rabbit 504 (17 months post)	post		[754]						

pre = pre-dosed sample

post = post-dosed sample

ND = Not Determined

D = Day after dosing

* Although there is no data for NRBS, the sample was considered positive due to strong reactivity.

Positive results are indicated in Bold based on the following ratio:

RU of post sample / RU of pre, NRS or NRBS sample ≥ 2.0

Correct

69/643458

Table 4. Reactivity of Commercial Type-Specific Adenovirus Antibodies to Immobilized Peptides

Vendor	Ab Specificity	Sample I.D.	Peptide:	Biosensor results in Response units (RU)						
				HVR1	HVR2	HVR3	HVR4	HVR5	HVR6	HVR7
Biogenesis	Goat anti-Ad2 hexon	post		25	3	17	3	5	15	15
Accurate	Murine anti-Ad penton (85 KD)	post		0	0	0	0	0	0	0
Biodesign	Goat anti-Ad2 hexon	post		30	10	ND	8	13	ND	ND
Biospecific	anti-Ad6	post		ND	ND	16	ND	ND	10	13
Biospecific	anti-Ad3	post		ND	ND	0	ND	ND	0	0
Lee Biol.	Rabbit anti-Ad5	pre post		0 [255]	0 0	0 8	0 0	0 0	0 8	0 10

20

pre = pre-dosed sample
post = post-dosed sample
ND = Not Determined

Positive results are indicated in Bold based on the following criteria:

- 1) Ratio of RU of post sample / RU of pre sample ≥ 2.0 OR
- 2) Post sample (without pre) with a binding greater than 50 RU

09/643458

21

Table 5. Reactivity of Pre-Clinical Serum Samples to Immobilized Peptides from Pigs that Received rAd5

Sample I.D.	Timepoint	Peptide:	Biosensor results in Response units (RU)						
			HVR1	HVR2	HVR3	HVR4	HVR5	HVR8	HVR7
377	pre		66	46	101	39	41	87	139
5	D15		[1085]	58	112	79	58	108	151
384	pre		73	71	89	52	57	98	129
8	D15		[785]	57	87	[131]	51	70	102
393	D29		[1820]	85	81	[111]	62	71	101
12	pre		86	189	83	83	100	65	80
12	D15		[493]	127	71	140	57	83	72
12	D28		[1490]	107	82	[201]	63	104	99
12	D48		[885]	113	107	[177]	94	86	91
389	pre		48	45	73	34	48	89	87
11	D13		[729]	39	52	32	50	53	64
11	D28		[1484]	61	62	[126]	68	58	80
11	D48		[1024]	88	61	[136]	65	54	84
380	pre		72	80	74	77	73	60	94
7	D15		[938]	64	70	62	56	60	81
7	D28		[1200]	66	89	75	60	58	76
385	pre		107	80	85	62	72	59	81
3	D18		[567]	49	41	41	42	40	55

pre = pre-dose sample

D = Day after dosing

Positive results are indicated in Bold based on the following ratio:
RU of post sample / RU of pre sample ≥ 2.0

005
09/643458

Table 8. Reactivity of Serum Samples to Immobilized Peptides from Patients with Non-Small Cell Lung Cancer Administered RAD5

Patient Initials	Timepoint	Peptide	Biosensor results in Response units (RU)						
			HVR1	HVR2	HVR3	HVR4	HVR5	HVR6	HVR7
ER	PRE		19	19	38	14	22	22	26
	D7		ND	ND	ND	ND	ND	ND	ND
	D14		26	27	41	21	29	24	31
	D21		21	22	37	17	18	21	27
	PRE		24	27	50	25	28	73	30
	D3		21	21	ND	20	23	ND	ND
	D7		388	17	ND	34	18	ND	ND
FK	D14		1161	34	55	29	37	83	32
	D21		645	33	48	34	34	68	25
	PRE		24	20	37	12	28	17	21
	D7		2045	14	ND	142	15	ND	ND
	D14		8286	25	37	101	25	17	21
	D21		7549	13	ND	167	9	ND	ND
	D28		18385	29	38	87	37	18	23
HH	ZMO.		2786	10	ND	18	9	ND	ND
	PRE		33	20	61	19	22	38	51
	D3		30	13	ND	13	5	ND	ND
	D7		80	22	ND	22	18	ND	ND
	D14		660	23	45	17	16	28	43
	D21		688	22	ND	15	9	ND	ND
	D28		433	25	41	18	20	27	38
MK	ZMO.		170	15	ND	9	5	ND	ND
	PRE		71	14	28	13	11	15	13
	D3		ND	ND	ND	ND	ND	ND	ND
	D7		14	16	29	16	32	16	14
SM	PRE		23	23	37	16	27	16	1026
	D8		108	20	40	14	21	20	523
	D27		173	12	29	9	11	19	ND
	D48		151	7	ND	4	11	ND	ND

D = Day after dosing
 ND = Not Determined
 pre = pre-dose
 MO. = Month's after dosing
 Positive results are indicated in Bold based on the following ratio:
 RU of post sample / RU of pre sample ≥ 2.0

09/643458

23

Table 7. Reactivity of Clinical Samples to Immobilized Peptide from Patients Administered rAd5

A. Patients with Recurrent & Malignant Head and Neck Cancer

Patient Initials	Timepoint	Peptide:	HVR1	HVR3	HVR4	HVR7
TGL	PRE		11	32	17	16
	D3		9	24	12	12
	D8		10	29	14	13
	D15		9	27	14	13
	D22		11	31	16	16
	D28		11	29	16	17
RWT	PRE		53	69	27	32
	D3		47	50	23	28
	D10		58	52	28	38
	D14		42	35	17	23

B. Patient with Recurrent Melanoma & Breast Cancer

Patient Initials	Timepoint	Peptide:	HVR1	HVR3	HVR4	HVR7
ES	PRE		27	27	24	20
	D3		23	26	20	18
	D7		54	27	23	19
	D14		252	28	22	18
	D21		185	28	21	18
	D28		79	15	10	8

C. Patient with Peritoneal Carcinomatosis

Patient Initials	Timepoint	Peptide:	HVR1	HVR3	HVR4	HVR7
VKA	PRE		7	35	16	12
	D2		10	33	17	18
	D3		8	30	13	17
	D7		14	49	26	17
	D14		41	36	16	29
	D21		45	44	25	26
	D28		38	31	16	25

09/64 3458

24

D. Patients with Hepatocellular Carcinoma

Patient Initials	Timepoint	Peptide:	HVR1	HVR3	HVR4	HVR7
JT	PRE		60	206	40	132
	D2		10	33	17	16
	D3		25	136	18	85
	D7		1628	109	27	73
	D14		7538	171	108	111
	D21		5208	187	102	116
	D28		3837	174	83	108
WMF	PRE		17	24	20	16
	D3		17	23	20	18
	D7		88	18	17	15
	D14		163	27	22	21
	D28		106	19	18	19
DFB	PRE		12	21	13	14
	D3		14	20	14	18
	D7		49	15	12	16
	D14		1226	26	14	19
	D21		608	22	10	14
RK	D28		414	32	19	23
	PRE		21	21	14	19
	D3		19	18	12	19
	D7		40	25	20	25
	D14		113	21	15	18
	D21		75	19	13	19
	D28		88	32	22	32

PRE = pre-dose

D = Day after dosing

Positive results are indicated in Bold based on the following ratio:

RU of post sample / RU of pre sample ≥ 2.0